

7 and are therefore subject to rejoinder pending allowance of the product claims in accordance with MPEP § 821.04 and *in re* Ochiai.

Priority

The Examiner stated that based on Applicant's priority statement filed on September 3, 2002 and an inspection of the parent application USSN 09/299,708 (filed on April 26, 1999), the Examiner concluded that the subject matter defined in claims 1-6 of the instant application has an effective filing date of January 10, 2001 (the filing date of the current application). This conclusion was based on the Examiner allegation that while the prior application disclosed the nucleic acid sequence of SEQ ID NO:2 encoding the polypeptide of SEQ ID NO:1, it fails to provide a patentable utility for the claimed invention.

35 U.S.C. § 102(a) Rejection of Claims 1, 2, 4 and 5

The Examiner has maintained the rejection of claims 1, 2, 4 and 5 under 35 U.S.C. § 102(a) as anticipated by Pallavicini et al. (December 21, 2000) for the reasons of record. The Examiner stated that, for the reasons cited above, the effective filing date of the current application has been determined to be January 10, 2001, and therefore the rejection is maintained.

Applicants submit that the Examiner has presented no evidence or sound scientific reasoning to support his allegation that the claimed invention is not supported by a patentable utility in the priority application cited under U.S.C. § 120, and therefore do not acquiesce to the grounds of the rejection. However, applicants submit with this a response a declaration under 37 CFR 1.131 signed by the sole inventor on the instant application, Dr. Michael G Walker, demonstrating that the claimed invention was conceived prior to the critical date for Pallavicini et al., December 21, 2000, and was diligently reduced to practice beginning from a time prior to December 21, 2000 until the filing date of the instant application, i.e., its constructive reduction to practice on January 10, 2001. Applicants therefore submit that Pallavicini et al. do not anticipate the claimed invention as recited in claims 1, 2, 4 and 5 and request withdrawal of the rejection of these claims under 35 U.S.C. § 102(a).

35 U.S.C. § 103(a), Rejection of Claims 3 and 6

103075 2 09/758,593



The Examiner has maintained the rejection of claims 3 and 6 under 35 U.S.C. § 103(a) as being unpatentable over Pallavicini et al. in view of Raju (U.S. Patent No. 6,261,818, filed April 14, 1999) for the reasons of record as set forth in the previous Office Action mailed May 9, 2002.

Applicants response to the rejection of claims under 35 U.S.C. § 102(a) as being anticipated by Pallavicini et al. have been discussed above. Raju does not teach or suggest a polynucleotide encoding SEQ ID NO:1 as recited in claim 1 and dependent claims 3 and 6. Applicants submit that for there to be a proper *prima facie* case of obviousness to a claim, the reference, or combination of references must teach or suggest all the claim limitations. Since Raju does not teach or suggest a polynucleotide encoding SEQ ID NO:1, Applicants submit that there is no proper *prima facie* case of obviousness against claims 3 or 6, and withdrawal of the rejection under 35 U.S.C. § 103(a) is therefore requested.

103075 3 09/758,593

Docket No.: PC-0025 CIP

CONCLUSION

In light of the above declaration and remarks, Applicants submit that the present application is fully in condition for allowance, and request that the Examiner withdraw the outstanding rejections. Early notice to that effect is earnestly solicited. Applicants further request that upon allowance of claims 1 and 3, that claims 7-12 be rejoined and examined as methods of use of the compositions of matter of claims 1 and 3 that depend from and are of the same scope as claims 1 and 3 in accordance with Ochiai and Brouwer. See MPEP § 821.04 and the Commissioner's Notice in the Official Gazette of March 26, 1996.

If the Examiner contemplates other action, or if a telephone conference would expedite allowance of the claims, Applicants invite the Examiner to contact Applicants' Agent of Record, below.

Applicants believe that no fee is due with this communication. However, if the USPTO determines that a fee is due, the Commissioner is hereby authorized to charge Deposit Account No. 09-0108, as set forth in the enclosed fee transmittal letter.

Respectfully submitted,

INCYTE GENOMICS, INC.

David G. Streeter, Ph.D.

Reg. No. 43,168

Direct Dial Telephone: (650) 845-5741

3160 Porter Drive

Palo Alto, California 94304

Phone: (650) 855-0555

Morenda 14, 2002

Fax: (650) 849-8886

. ئىي

Certificate of Mailing

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, Washington DC 20231 on 1119

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Michael G. Walker

Title:

ANKYRIN REPEAT DOMAIN 2 PROTEIN VARIANT

Serial No.:

09/758,593

Filing Date:

January 10, 2001

Examiner:

Li, R.

Group Art Unit:

1646

Commissioner for Patents Washington DC 20231

DECLARATION UNDER 37 CFR 1.131

RECEIVED

NOV 2 0 2002

TECH CENTER 1600/2900

The purpose of this declaration is to establish conception combined with diligence in this application in the United States at a date prior to the earliest public availability date (December 21, 2000)) of the following prior art reference cited by the Examiner: Pallavicini et al. (GenBank Accession No. AJ304805, December 21, 2000).

I the undersigned inventor, Michael G. Walker declare and state that:

- 1. I am the inventor on the polynucleotide invention, claims 1, 2, 4 and 5 claimed in USSN. 09/758,593, filed in the United States Patent and Trademark Office on January 10, 2001 This application is a continuation-in-part of USSN. 09/299,708, filed on April 26, 1999
- 2. The invention, claimed at least in pending claims 1, 2, 4 and 5 of the above-identified application, was conceived prior to December 21, 2000, in this country.
- 3. The invention was diligently reduced to practice from the conception of the invention to the filing of the above-identified application, USSN.09/758,593
- 4. Exhibit A is a copy of pp.26 and 37 of the Sequence Listing for USSN 09/299,708, filed on April 26, 1999, showing the polynucleotide (SEQ ID NO:48) and its encoded protein, (SEQ ID NO:62) for Incyte ID No. 5578191 corresponding to SEQ ID NO:2 and SEQ ID NO:1, respectively, of the instant

application. (Please note that in this and subsequent Exhibits, technical and other information not relevant to this Declaration have been blocked out.) Exhibit A therefore shows conception of the claimed invention prior to the critical date of December 21, 2000 Following conception, the claimed invention was diligently reduced to practice, as detailed below.

- 5. Exhibit B is a copy of a docket sheet, dated November 9, 2000, documenting the assignment of a docket number to the above-identified application in anticipation of filing. It is standard practice at Incyte that assignment of a docket number occurs concurrently with drafting and preparation of the application.
- 6. Exhibit C is a database printout dated December 4, 2000 showing the Tissue distribution analysis for SEQ ID NO:2 from the LIFESEQ database, data that was used to generate Figure 3A of the specification.
- 7. Exhibit D is a database printout also dated December 4, 2000 showing the expression of SEQ ID NO:2 in tissue libraries from the musculoskeletal system in the LIFESEQ database, data that was used to generate Figure 3B of the specification.
- 8. Exhibit E is a copy of the Official Filing Receipt indicating that the above-identified application was filed with the U.S.P.T.O. on January 10, 2001.
- 8. The above Exhibits demonstrate conception of the present invention prior to the critical date of December 21, 2000 Additionally, the above Exhibits show diligence in reducing the present invention to practice from prior to December 21, 2000, until the filing date of the above-identified application, i.e., the constructive reduction to practice on January 10, 2001.

9. The undersigned further declares that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true, and that these statement were made with the knowledge that willful false statements and the like so made are punishable by fine, imprisonment, and/or both under Section 1001 of Title 18 of the United States Code, and that such willful false statement may jeopardize the validity of any application or patent issued thereon.

Date: 12 Nov 02

Michael G. Walker

1050 Borregas Avenue #80 Sunnyvale, California 94089

Exhibit A Page 1 of 2



<212> DNA

<213> Homo sapiens

<220> -

<223> 5578191CB1

<400> 48

cagctcgagg gacggcacca tggaggactc cgaggcggtg cagagggcca cagcgctcat 60 cgagcagegg ctggcacagg aggaggagaa tgagaaactc cgaggagaca cacgccagaa 120 gctgcccatg gacttgctgg tgctggagga tgagaagcac cacggggctc agagtgcagc 180 cctgcagaag gtgaagggcc aagagcgcgt gcgcaagacg tccctggacc tgcggcggga 240 gatcatcgat gtgggcggga tccagaacct catcgagctg cggaagaaac gcaagcagaa 300 gaagegggae getetggeeg eetegeatga geegeeecea gageeegagg agateaetgg 360 ccctgtggat gaggagacct tcctgaaagc tgcggtggag gggaaaatga aggtcattga 420 gaagtteetg getgaegggg ggteageega eacgtgegae eagtteegte ggaeageaet 480 gcaccgagct tccctggaag gccacatgga aatcctggag aagcttctag ataatggggc 540 cactgtggac ttccaggatc ggctggactg cacagccatg cattgggcct gccgcggggg 600 ccacttagag gtggtgaaac ttctgcaaag ccatggagca gacaccaatg tgagggataa 660 gctgctgagc accccgctgc acgtggcagt ccggacaggg caggtggaga ttgtggagca 720 ctttctatcc ctgggcctgg aaatcaatgc cagagacagg gaaggggata ctgccctgca 780 tgacgctgtg aggctcaacc gctacaaaat catcaaactg ctgctcctgc atggggctga 840 catgatgacc aagaacctgg caggaaagac cccgacggac ctggtgcagc tctggcaggc 900 tgatacccgg cacgccctgg agcatcctga gccgggggct gagcataacg ggctggaggg 960 gectaatgat agtgggegag agaceeetea geetgtgeea geeeagtgaa tgegtgeeee 1020 agcccagcca gctacccagc ccctctctgt gtgcagccgg agggtcctaa gaatggctcc 1080 cggagctaac tgagggccca gcctttttc tgcatgatcc aggagcacat accacaaact 1140 accacaataa aaaagctg 1158

<210> 49

<211> 70

<212> PRT

<213> Homo sapiens

<220> -

<223> 3601719CD1

<400> 49

 Met
 Leu
 Glu
 Pro
 Ser
 Arg
 Gln
 Ile
 Ser
 Ile
 Phe
 Gln
 Trp
 Glu
 Pro
 15

 Phe
 Gly
 Gln
 Gln
 Val
 Asn
 Pro
 Pro
 Glu
 Lys
 Asn
 Val
 Leu
 Pro
 Pro
 Arg
 Met
 Arg
 Arg
 Arg
 Arg
 Arg
 Asn
 Phe
 Gln
 Asp
 Leu
 Brown
 Asp
 Leu
 Gln
 Asp
 Leu
 Ile
 Asp
 Ile
 Leu
 Lys
 Val
 Asn
 Asn
 From the contraction of the

<210> 50

<211> 552

<212> PRT

<213> Homo sapiens

<220> -

<223> 3445829CD1

<400> 50

 Met
 Ser
 Thr
 Phe
 Gly
 Tyr
 Arg
 Gly
 Leu
 Ser
 Lys
 Tyr
 Glu
 Ser

 1
 5
 10
 15

 1e
 Asp
 Glu
 Leu
 Leu
 Ser
 Leu
 Ser
 Ala
 Glu
 Glu
 Leu

 20
 25
 30

 Lys
 Glu
 Leu
 Glu
 Asp
 Ile
 Glu
 Pro
 Asp
 Asp

 35
 40
 45



PB-0009 US

Docket No.: PC-0025 CIP Serial No.: 09/758,593

Exhibit A Page 2 of 2

Asp Gln Arg Gly Leu His Ser Val Gly Arg Lys Asp Leu Ser Pro 190 Pro Gly Ala Gly Glu Pro

<210> 62 <211> 329 <212> PRT <213> Homo sapiens <220> -<223> 5578191CD1 <400> 62 Met Glu Asp Ser Glu Ala Val Gln Arg Ala Thr Ala Leu Ile Glu Gln Arg Leu Ala Gln Glu Glu Glu Asn Glu Lys Leu Arg Gly Asp 20 25 Thr Arg Gln Lys Leu Pro Met Asp Leu Leu Val Leu Glu Asp Glu 35 40 Lys His His Gly Ala Gln Ser Ala Ala Leu Gln Lys Val Lys Gly 55 Gln Glu Arg Val Arg Lys Thr Ser Leu Asp Leu Arg Arg Glu Ile 75 Ile Asp Val Gly Gly Ile Gln Asn Leu Ile Glu Leu Arg Lys 80 85 Arg Lys Gln Lys Lys Arg Asp Ala Leu Ala Ala Ser His Glu Pro 95 100 Pro Pro Glu Pro Glu Glu Ile Thr Gly Pro Val Asp Glu Glu Thr 110 115 Phe Leu Lys Ala Ala Val Glu Gly Lys Met Lys Val Ile Glu Lys 125 130 135 Phe Leu Ala Asp Gly Gly Ser Ala Asp Thr Cys Asp Gln Phe Arg 140 145 Arg Thr Ala Leu His Arg Ala Ser Leu Glu Gly His Met Glu Ile 155 160 Leu Glu Lys Leu Leu Asp Asn Gly Ala Thr Val Asp Phe Gln Asp 170 175 Arg Leu Asp Cys Thr Ala Met His Trp Ala Cys Arg Gly Gly His 185 190 Leu Glu Val Val Lys Leu Leu Gln Ser His Gly Ala Asp Thr Asn 200 205 Val Arg Asp Lys Leu Leu Ser Thr Pro Leu His Val Ala Val Arg 215 220 Thr Gly Gln Val Glu Ile Val Glu His Phe Leu Ser Leu Gly Leu 230 235 Glu Ile Asn Ala Arg Asp Arg Glu Gly Asp Thr Ala Leu His Asp 245 250 255 Ala Val Arg Leu Asn Arg Tyr Lys Ile Ile Lys Leu Leu Leu 260 265 270 His Gly Ala Asp Met Met Thr Lys Asn Leu Ala Gly Lys Thr Pro 275 280 285 Thr Asp Leu Val Gln Leu Trp Gln Ala Asp Thr Arg His Ala Leu 290 295 Glu His Pro Glu Pro Gly Ala Glu His Asn Gly Leu Glu Gly Pro

305

320

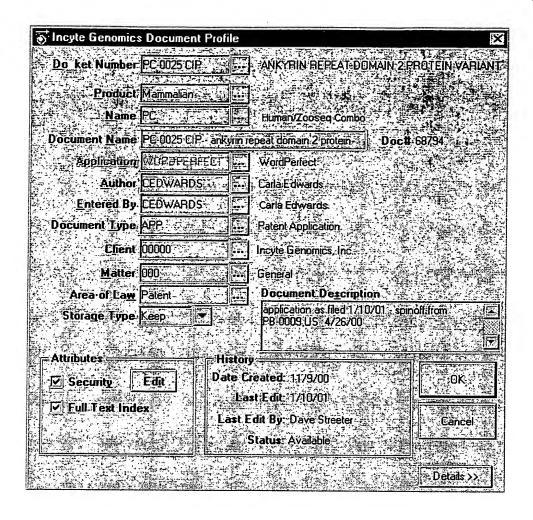
310

325

Asn Asp Ser Gly Arg Glu Thr Pro Gln Pro Val Pro Ala Gln

Docket No.: PC-0025 CIP Serial No.: 09/758,593

Exhibit B Page 1 of 1



Docket No.: PC-0025 CIP Serial No.: 09/758,593

> Exhibit C Page 1 of 1





Gene Detail

Confidential -- Property of Incyte Genomics, Inc. LifeSeq Gold 5.1 Sep2000

Gene Information

Gene ID: 337941
Top Hit ID: g5420272
Hit Type: Homolog

Template Count: 2
Hit Species: Mu:
E-Value: 8.

Mus musculus 8.0e-41 Po Pct ID: Verified Reagent: Y

Gene Description: skeletal muscle and cardiac protein

Genomic Data

Templates

Template ID Template Description Top Hit ID Bit Species E-Value 337941.3 skeletal muscle and cardiac protein g5420272 Mus musculus 2.0e-09 84 995 **⋥** ● <u>337941.1</u> skeletal muscle and cardiac protein g5420272 9.0e-41 43 1187 64

Uncheck All

Submit template IDs to BLASTZ Submit Submit Reset

Protein Function

No Protein Function found

Tissue Distribution

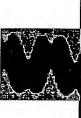
Tissue Category	Clone Count	Found in	Abs Abund	Pct Abund	Pct Spac
Cardiovascular System	266190	4/68	4	0.0015	6.44
Connective Tissue	144645	0/47	0	0.0000	0.00
Digestive System	501101	1/148	1	0.0002	0.86
Embryonic Structures	106713	0/21	0	0.0000	0.00
Endocrine System	225386	2/53	2	0.0009	3.86
Exocrine Glands	254635	0/54	0	0.0000	0.00
Genitalia, Female	427284	0/106	0	0.0000	0.00
Genitalia, Male	448207	3/114	7	0.0016	6.87
Germ Cells	38282	0/5	0	0.0000	0.00
Hemic and Immune System	680277	0/159	0	0.0000	0.00
iver	109378	9/35	0	0.0000	0.00
fusculoskeletal System	159280	10/47	24	0.0151	64.81
Mervous System	955753	4/198	5	0.0005	2.15
Pancreas	110207	0/24	0	0.0000	0.00
espiratory System	390086	1/93	2	0.0005	2.15
Sense Organs	19256	0/8	0	0.0000	0.00
kin	72292	0/15	0	0.0000	0.00
tomatognathic System	12923	0/10	0	0.0000	0.00
nclassified/Mixed	120926	1/11	1	0.0008	3.43
rinary Tract	279062 ⁻	4/64	6	0.0022	9.44
otals	5321883	30/1292	52	0.0010	100.00

Requested by: LG051_092000_GOLD_RO on Mon Dec 04 10:22:59 2000

Library Distribution



Library Distribution



Help

Sequences

Genomic Data

Library Comp

Libraries

Genes

Main Menu

Confidential -- Property of Incyte Genomics, Inc. LifeSeq Gold 5.1 Sep2000

Template ID: 337941.1

Template Description: skeletal muscle and cardiac protein Tissu Category: Musculoskeletal System

in: F und

	_		Abs	Pot	P C C
TIDEBEN ID	Count	Library Description	Abund	Abund	Spec
MUSCNOT10	3302	muscle, gluteal, mw/clear cell SAR, 43F	11	11 0.3331	25 55
MUSLTDT01	804	muscle, thigh, mw/lipoSAR, 58M	-	0.1244	
MUSCNOT02	2541	muscle, psoas, 12M	۳ ا	0.1241	00.0
MUSLNOT01	3306	muscle, tibial, aw/thrombosis, 41F		0 0605	0 7 0
MUSLTDR02	4002	muscle, thigh, mw/lipoSAR, 58M, RP	1 (0.050	# · o
MUSCNOM01	2716	muscle, skeletal, mw/malignant hyperthermia wm/wn) (0.0360	
MUSCDINO6	3043	muscle, thigh, ALS, 74F, NORM	⊦-	0.0388	4.74
MUSCDMT01	3137	muscle, calf, mw/gangrene, aw/atherosclerosis 67M	-	0.0329	\$0.7 50.0
MUSCDITO6	3192	muscle, skeletal, aw/Krabbe, 11mF	- t	0.0313	7.50
MUSCNOT07	6491	muscle, forearm, mw/intramuscular hemangioma 38F	1 [0.0154	1 25

Not found in:

	<u>Library Description</u>	bone, aw/cancer, TIGR	bone tumor, Ewing's SAR, CGAP	bone tumor, mets prostate cancer, M. 3' CGAP	bone tumor/line, MG-63, osteoSAR/giant cell M/F nool pp	osteogenic tumor line, Saos-2, SAR, 11F untreated	bone, trabecula/femoral neck 66M t/nexx BMD_2_18h	bone tumor, sacrum, giant cell timor 18F 5pp	bone, rib, aw/Patau's, fetal, 20wM. lg CDNA
CTODE				3244	1960	8909	862	1753	5401
	Library ID	BONENOP01	BONETUP01	BONETUP02	BONEUNR01	BONEUNT01	BONFTXT01	BONMTUE02	BONRFEC01

http://summit.incyte.com/cgi-bin/LifeSeqGold/LG_LibDist?SeqSource=LG&SeqID= 337941.1&SeqVersion=1&schemaOwner=LG051_092000_GOLD&TisCat=317

04 10:26:45 2000 Requested by: LG051_092000_GOLD_RO on Mon Dec









UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231

							www.uspic.gov
APPLICATION NUMBER	FILING DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	DRAWINGS	TOT CLAIMS	IND CLAIMS
09/758,593	01/10/2001	1646	840	PC-0025	12	20	3

27904 INCYTE GENOMICS, INC. 3160 PORTER DRIVE PALO ALTO, CA 94304 CONFIRMATION NO. 9627
CORRECTED FILING RECEIPT

OC000000008682568

Date Mailed: 08/26/2002

Receipt is acknowledged of this nonprovisional Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Filing Receipt Corrections, facsimile number 703-746-9195. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the r ply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

Applicant(s)

Michael G. Walker, Sunnyvale, CA;

Domestic Priority data as claimed by applicant

THIS APPLICATION IS A CIP OF 09/299,708 04/26/1999 ABN

Foreign Applications

If Required, Foreign Filing License Granted 03/28/2001

Projected Publication Date: 07/11/2002

Non-Publication Request: No

Early Publication Request: No

Title

Ankyrin repeat domain 2 protein variant

Preliminary Class

435